

Press Release

International Landmark EAST Study Investigates Treatment Options for Atrial Fibrillation: First patient enrolled on July 28, 2011

Largest pan-European study to determine whether an early comprehensive rhythm control strategy for the treatment of atrial fibrillation (AF) will benefit patients.

The German Competence Network on Atrial Fibrillation (AFNET), the European Heart Rhythm Association (EHRA), (a registered branch of the European Society of Cardiology), Sanofi and St. Jude Medical have joined forces to conduct the EAST (**E**arly comprehensive **A**trial fibrillation **S**troke prevention **T**rial) clinical trial. This investigator-initiated study seeks to determine whether an early, comprehensive, standardized rhythm control therapy can help prevent adverse cardiovascular outcomes associated with atrial fibrillation (AF), including stroke and death. More specifically, EAST study will evaluate whether an early and comprehensive rhythm control treatment of patients with early onset AF leads to better patient outcomes than usual care alone.

The sponsor of EAST is AFNET (German Atrial Fibrillation Competence Network). EHRA (European Heart Rhythm Association) is an equal scientific partner in the trial. Sanofi and St. Jude Medical have provided grants to support the conduct of the trial. The investigators plan to enroll more than 3000 patients from 200 centers in 11 European countries. The first patient was enrolled on July 28, 2011, in Hamburg, Germany.

EAST Trial Background

EAST is a prospective, parallel-group, randomized, open, blinded, end-point assessment trial. The multicenter study seeks to understand whether improved rhythm control therapy could prevent death and stroke. Specifically, whether an earlier initiation of rhythm control therapy, when included in a comprehensive AF management strategy, has the potential to maintain the heart's rhythm more effectively, prevent AF-related complications, and disrupt the cycles that maintain AF and cause complications.

Commenting on the need for the EAST study, Prof. Dr. Paulus Kirchhof, coordinating investigator of the trial said: "The trial is based on the observation that insufficient, non-structured and delayed therapy of the multiple factors that maintain AF and cause its complications has most likely contributed to the limited effectiveness of rhythm control interventions in past trials. This trial takes an important step forward to learn more about the value of rhythm control therapy to improve the lives of AF patients."

Patients with recent-onset AF at risk for stroke or death are eligible for the trial. Participants will be randomized to either an “early, comprehensive, standardized” intervention to maintain sinus rhythm on top of usual care, or to “usual care” alone. Early intervention will include antiarrhythmic drug therapy and/or pulmonary vein isolation (PVI) using catheter ablation as well as ECG monitoring of therapy. Usual care follows standardized therapy under the 2010 ESC guidelines for the treatment of AF.

The primary outcome of EAST is the composite of cardiovascular death, stroke and heart failure or acute coronary syndrome (hospitalization). There will be outpatient follow-up at 12, 24 and 36 months.

Günter Breithardt (AFNET speaker), Angelo Auricchio, and Panos Vardas (current and past EHRA president) said in a joint statement today: “Investigator-initiated clinical research with a relevant impact requires good ideas, perseverance, a network of colleagues, but also financial resources. As sponsor and co-organiser of the EAST trial, we therefore highly appreciate the financial support from St. Jude Medical and Sanofi-Aventis to make this important clinical research possible.”

Background information: atrial fibrillation

AF is a condition in which the upper chambers of the heart (atria) beat rapidly and erratically, affecting the heart’s ability to adequately pump blood to its lower chambers (ventricles) and subsequently to the rest of the body. Some of the complications caused by AF are increased risk of death or stroke, increased severity of stroke, increased hospitalizations, and reduced quality of life due to palpitations and other AF-related symptoms. The disease affects between one and two percent of the European population.

AF can have an impact on the heart as early as a few weeks after onset, causing cycles of remodeling, dysfunction and additional triggers which lead to the progression of the disease. These cycles both maintain and perpetuate AF from the state of initial detection, to paroxysmal (AF that begins suddenly and ends spontaneously) to persistent (recurring episodes lasting more than seven days) to permanent (ongoing and long term).

The German **Competence Network on Atrial Fibrillation (AFNET)** is an interdisciplinary research network located in Germany. AFNET aims at improving care of patients with atrial fibrillation by promoting research, medical services and information in emerging diagnostic and therapeutic fields in atrial fibrillation. The network has been funded by the German Federal Ministry of Research and Education since 2003. <http://www.kompetenznetz-vorhofflimmern.de>

The **European Heart Rhythm Association (EHRA)** is an association specialising in electrophysiology and was created from the merger of two former Working Groups of the European Society of Cardiology on 'Cardiac Pacing' and on 'Arrhythmias'. Its goal is to serve as the leading organisation in the field of arrhythmias and electrophysiology in Europe, and to attract all physicians from Europe and beyond to foster the development of this area of expertise.

<http://www.escardio.org/EHRA>

Sanofi, a global and diversified healthcare leader, discovers, develops and

distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, rare diseases, consumer healthcare, emerging markets and animal health. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

About St. Jude Medical

St. Jude Medical develops medical technology and services that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. The company is dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient. St. Jude Medical is headquartered in St. Paul, Minn. and has four major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. For more information, please visit sjm.com.

Further information:

ClinicalTrials.gov: NCT01288352

<http://clinicaltrials.gov/ct2/show/NCT01288352?term=NCT01288352&rank=1>

ISRCTN: ISRCTN04708680

<http://www.controlled-trials.com/ISRCTN04708680/ISRCTN04708680>

EAST Website

<http://www.easttrial.org>

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